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IN THE

Supreme Court of the United States

OCTOBER TERM, 1962

No. 911

MILLPAX, a Corporation, and
ROY F. PAXTON, an Individual, *Petitioners,*

v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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REGULATIONS

General Regulations, Food, Drug, and Cosmetic Act, Title 21, Code of Federal Regulations, Part 1 (Sec. 403(j)), 52 Stat. 1048; 21 U.S.C. 343(j) 11

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To the Honorable, the Chief Justice of the
United States and the Associate Justices of
the Supreme Court of the United States:

Petitioners, Millpax, Inc., a corporation, and Roy F. Paxton, an Individual, respectfully pray that a writ of certiorari issue to the United States Court of Appeals for the Seventh Circuit to review a final judgment of that Court, affirming judgments of the United States District Court, Southern District of Illinois, Southern Division, convicting Defendants on Counts III and V, of a five count Indictment.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit, dated January 15, 1963, is not yet reported, but a copy thereof is attached to this petition as Appendix hereto.

The judgments of the United States District Court, Southern District of Illinois, Southern Division, are found at pages 135-138, Appendix to Brief for Defendants-Appellants, and also filed here.

JURISDICTION

Petition for rehearing was filed by the Defendants-Appellants with the United States Court of Appeals for the Seventh Circuit, on January 24, 1963. By order dated February 21, 1963, a copy of which is attached to this petition as Appendix hereto, the appellate court changed its Opinion of January 15, 1963, in certain respects as indicated, but denied petition for rehearing.

Motion for stay of mandate for a period of 30 days, pending application for writ of certiorari to the Supreme Court of the United States, was filed by Defendants-Appellants with the United States Court of Appeals for the Seventh Circuit, on February 26, 1963. Pursuant thereto, the Court by Order entered February 27, 1963, granted Motion for stay of mandate for a period of 20 days only.

Jurisdiction is conferred on the Supreme Court of the United States by U.S.C. Title 28, Section 1254, to review this cause by writ of certiorari.

QUESTIONS PRESENTED FOR REVIEW

Five important federal questions presented herein are:

1. Whether a vendor of a food product for special dietary purposes, as so defined by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), can be held answerable for the unsolicited praise of users of the product, even though mistaken, where the vendor did not make use of the commendations in furthering the sale and distribution of the product?

2. Whether a vendor of a food product is obliged to take positive action to negate or disclaim such praise, where the commendations are incorporated in a magazine article, the preparation and publication of which were without the knowledge or sanction of the vendor?

3. Whether government agents, employing the stratagem of posing as ordinary customers, in ordering such product by mail for faked ailments, and making reference to the magazine article, aforesaid, imputes to the vendor therapeutic claims for the product, thereby classifying the preparation ipso facto into the category of a drug?

4. Whether the conclusion by an appellate court that an accused would have committed an act violative of a federal statute, is sufficient to support a conviction for the violation of that provision of the Act which prohibits the introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded? (Sec. 301(a), Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 et seq.).

5. Whether an appellate court can properly refuse to consider for the first time on the appellate level the question of entrapment as a matter of law, even though it results in a miscarriage of justice?

THE STATUTE INVOLVED

The statute involved in the determination of the questions is the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

STATEMENT OF THE CASE

This cause concerns a food product for special dietary use, registered as such in the U. S. Patent Office, and neither deleterious nor harmful to consumers. It is properly labeled in accordance with the labeling requirements of the Act, as a food product for special use.

The first question concerns the issue of whether a vendor of a product can be held answerable for the unsolicited praise of the product, if the vendor does not exploit such commendations in promoting the sale of the product.

In March, 1960, one Don Machem prepared, and caused to be published in a magazine called the "Herald of Health," an article containing in substance praises by users of the product (known as "Millrue"), as to the value of this preparation in the instance of certain human ailments. The Petitioners herein were without knowledge of the preparation of this magazine article, nor were they aware of its existence until it appeared in the aforesaid publication. There is no evidence in the record that the claims in the article were used by the Petitioners in the labeling for Millrue.

The second question concerns the character of the responsibility, if any, that a vendor of a product is obliged to assume, for the mistaken praise of users of the product in the instance of human ailments, where such commendations were not exploited by the vendor for its benefit.

When the Petitioners herein were aware of the published article, aforesaid, they immediately took action to negate or disclaim the claims appearing in the article for the product "Millrue", by directing counsel to prepare a letter of disclaimer, in the text quoted below, which document was mailed to those who were prompted by the article to inquire about, and/or order Millrue:

> Many thanks for your letter and order and it is regretted that Mr. Paxton cannot write to you personally as the mail has been tremendous and the Company is a small one.
>
> Your interest in the article referred to is natural, but terming the product a 'blood purifier' therein is a misnomer. To 'purify' connotes that as to any particular substance it is freed from extraneous matter or from anything that debases, pollutes, or contaminates it. The blood may be variable through bodily functions, or malfunctions, and by ingestion, deficiencies when existent may be aided.
>
> If you will again read the article referred to which was written by Don C. Matchan, you will find that no claim is made that the product cures anything, either by the writer or the manufacturer. Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom.
>
> If you still desire to order please advise by return mail, otherwise your money will be returned to

you, as there is no desire by the manufacturer to sell this product under false pretenses.

The third question concerns the stratagem employed by two government agents, posing as ordinary customers, who addressed letters to the Petitioners herein, referring to the magazine article, aforesaid, and ordering Millrue for faked ailments.

Agent Charles A. Armstrong, an inspector of the Federal Food and Drug Administration, addressed a letter on May 2, 1960, from Memphis, Tennessee, to the Petitioners in Carlock, Illinois, as follows:

> I read about your cancer cure—Millrue—in the March, 1960 issue of Herald of Health.
>
> I am enclosing a $10 money order for two bottles of the Millrue.
>
> I have just been told that I have cancer of the throat that cannot be cured without an operation, but I'd rather take medicine if it can cure me also.

Upon receipt of a letter of disclaimer, above quoted, Agent Armstrong replied:

> I received your letter of May 6.
>
> Please send me the two bottles of Millrue that I ordered.

Agent Jack B. Forbragd, an inspector of the Federal Food and Drug Administration, addressed a letter on May 6, 1960, from San Francisco, California, to the Petitioners herein, as follows:

> A good friend just showed me a wonderful article in Herald of Health Magazine about how you make a herb medicine to cure cancer called Millrue. I have stomach pains and constipated and I am sure it is cancer because my neighbor had it just like

> this and they just sewed her up and sent her home to die. I don't know much tax is there so will send 20 cents like it is in California. Please send a bottle of Millrue right away.

The record is in conflict as to whether Agent Forbragd received Petitioners' disclaimer reply, or whether this government representative in an alleged telephone conversation with the Petitioners herein insisted on the shipment of the product despite Petitioners' disclaimer during the conversation that "we do not sell any medicine for any disease of any kind."

Based solely on the above exchange of communication between the government agents and the Petitioners, the government insisted, and the United States Court of Appeals for the Seventh Circuit concluded, that the letter of disclaimer "was framed with the intention of drawing a cloak of legality around defendants' transactions," and that it was "obvious that defendants intended to be understood as adopting as their own the magazine testimonials." Further, according to the appellate court, it was "the intention of the defendants * * * to have prospective purchasers regard it as a drug and so use it; hence, their own actions classified Millrue as a drug."

The fourth question concerns the degree of positiveness of the Act necessary to constitute a violation of Sec. 301(a) of the Federal Food, Drug, and Cosmetic Act, as Amended, (21 U.S.C. 301 et seq.), which prohibits the introduction into interstate commerce of any drug that is misbranded.

The essential elements for the violation are therefore that the product be a drug, in a misbranded state, and that interstate commerce must be established. Despite

these essentials, the appellate court herein, in its amended opinion (Appendix hereto), stated:

> We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that the government agents used a ruse to conceal their identity does not require a different conclusion.

The record in the case fails to include a scintilla of evidence of any positive sale on the part of Petitioners, of the product to any ordinary purchasers in a misbranded state.

The fifth question to be considered, concerns entrapment as a matter of law.

The ruse adopted by the government agents herein, was prompted solely by the praises of Millrue users, appearing in a magazine article, neither prepared nor published by Petitioners, nor made use of in furthering the sale of the product.

The sole practices complained of by the government are limited to the two transactions between the Petitioners and two government agents, who induced the Petitioners by stratagem to sell Millrue. No evidence was developed that the Petitioners were otherwise engaged in criminal activity. On the contrary, the only acts complained of were those, the commission of which, was induced by the ruse of the agents. The Petitioners, at the appellate level, raised for the first time the defense of entrapment as a matter of law on the ground that otherwise the result would lead to a miscarriage of justice. The appellate court concluded in this re-

spect, that the issue of entrapment was properly left to the jury. (Opinion, p. 7, Appendix hereto).

The Petitioners herein were found guilty after trial by jury on three counts of a five-count indictment charging them with the misbranding of a drug known as "Millrue," in that the labeling failed to bear adequate directions for use, as required by Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 352 (f)(1), and with causing the introduction or delivery for introduction into interstate commerce of such preparation, so labeled, in violation of Section 301(a) of the Act, 21 U.S.C. 331(a), which prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded.

The judgment entered by the District Court convicting defendants on Counts III and V, of the Indictment, which Counts concerned the Armstrong and Forbragd transactions, respectively, was affirmed by the United States Court of Appeals for the Seventh Circuit, the Court reversing the conviction by the lower court on Count IV.

REASONS FOR GRANTING OF THE WRIT

One primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that this case raises important questions of federal law concerning the interpretation of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as Amended, 21 U.S.C. 301, et seq. This section of the Act provides that a drug is deemed to be misbranded unless its labeling bears adequate directions for use. The principal question concerned in the case at bar is whether the acts of

government agents posing as ordinary customers, can be imputed to a vendor so as to constitute therapeutic claims for the product involved.

A second primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the decision of the court below is in conflict with applicable decisions of this Court, and in conflict with the decision of another court of appeals on the same matter. The court below, in its decision with respect to the instant cause, held the Petitioners herein answerable for the mistaken praises of others as to their product, despite the fact that the Petitioners did not make use of these praises in promoting the sale of the preparation. An applicable decision by the Supreme Court of the United States established that a shipper cannot be made answerable for the mistaken praise of others as to the product concerned, if such praise is not exploited to the shipper's profit. *United States* v. *Johnson,* 177 Fed. 313, 221 U.S. 488, 31 S. Ct. 625, 55 L. Ed. 823.

A third primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the appellate court below refused to consider as an assigned error the defense of entrapment as a matter of law, for the first time on appeal, despite the fact that the result would lead to a miscarriage of justice. *United States* v. *Sferas,* 210 F.2d 69, 71 (C.A. 7, 1954), cert. den. 347.

Entrapment, as a matter of law, was established in the present cause, and the Petitioners, otherwise innocent, were induced to commit the acts complained of. *Sherman* v. *United States,* 356 U.S. 369, 373 (1958). Also, *Johnson* v. *United States* (U. S. Court of Appeals for the District of Columbia Circuit, No. 16890, decided Feb. 14, 1963), not yet reported.

ARGUMENT

The Petitioners herein manufactured and sold a food product known as Millrue, and so registered as such with the U. S. Patent Office. Its label satisfied the requirements of the Federal Food, Drug, and Cosmetic Act, as Amended (21 U.S.C. 301, et seq.). Such a product can properly be used in the dietary treatment of disease. (Section 1.11, General Regulations, Food, Drug, and Cosmetic Act, Title 21, Code of Federal Regulations, Part I (Sec. 403(j), 52 Stat. 1048; 21 U.S.C. 343(j)).

The Federal Food and Drug Administration initiated its action against the Petitioners herein as a result of the article appearing in the March 1960 issue of the magazine "Herald of Health." The District Court herein refused to admit into evidence the context of this article. The stratagem employed by the Agency took the course of approaches by two government agents, posing as ordinary customers with fictitious ailments, addressing letters to the Petitioners herein, referring to the magazine article and ordering Millrue for certain diseases.

The government was confronted with the problem of establishing that Millrue, although a food product properly labeled as such, was being introduced into interstate commerce by the Petitioners as a drug.

The government did not contend that the exchange of communications between the government agents and the Petitioners herein constituted labeling. Labeling, as defined by the Act means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. (Sec. 201(1), Federal Food, Drug, and Cos-

metic Act, as Amended, 21 U.S.C. 301 et seq.). The government did, however, regard this exchange of communications as a highly relevant source "that may be considered in determining the conditions and purposes for which Appellants sell Millrue." That the Court may look to all relevant sources in order to ascertain what was the intended use of a product, is not denied, nor is it the argument of the Petitioners herein that relevant sources are confined to labels on the product or its labeling. Relevant sources were referred to in *V. E. Irons et al* v. *United States*, 244 F. 2d 34, 44 (C.A. 1, 1957), cert. den. 354 U.S. 923, as oral representations to users, and printed circulars. In *United States* v. *10 Cartons* . . . 152 F. Supp. 360, 368 (W.D. Pa. 1957), relevant sources were characterized as impressions created by oral representations, advertisements, and other sources upon the person to whom the representations are directed.

In the cause at bar, Agents Armstrong and Forbragd, by initially addressing the Petitioners herein, as aforesaid, set in motion forces which the government considered as creating the impression that Millrue was intended by the Petitioners for use in the treatment of diseases.

The record contains no proof that such was the impression of ordinary customers. Try as it might, the government failed to produce a single ordinary customer who could testify of such an impression. The case then turned on the efforts of two government agents who faked diseases, and ordered Millrue for these ailments with full knowledge that the product was without value in the treatment of diseases. Despite a disclaimer by the Petitioners herein that Millrue

would not cure anything, the government convinced the appellate court that the Petitioners had thereby given the impression that the product was intended for use in the treatment of disease.

Proceeding on that theory, the appellate court herein, held in its amended decision—

> We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that the government agents used a ruse to conceal their identity does not require a different conclusion. (Appendix hereto).

Even positive expressions by a vendor which give rise to the question of intent, in a case such as this is, must not be interpreted through the minds of experts, but rather, the effect of such impressions, if any are created for which the creator is responsible, must be interpreted through the minds of ordinary customers.

Agents Armstrong and Forbragd were neither savants nor dolts, and they did not purchase Millrue in the belief that this product had curative properties in the treatment of diseases in man.

The Federal Food, Drug, and Cosmetic Act, as Amended, 21 U.S.C. 301 et seq.), is a criminal statute that should be strictly construed and applied. The Congress, at no time during the debates concerning the Act, asserted or pretended that it was proposed to reach the matter of holding manufacturers and vendors of preparations to criminal liability for misstatements of others as to the curative or remedial effects of the preparations; that had such been the intent, apt words, both in the title and body of the Act, could and should

have been easily employed to indicate such purpose, and not leave it to the courts by strained construction to read it into the statute. *United States* v. *Johnson*, supra, 177 Fed. 313, 221 U.S. 488, 31 S. Ct. 627, 55 L.Ed. 823.

The Petitioners herein recognize that the *Johnson* case primarily held that the original misbranding provisions of the 1906 Act did not cover therapeutic claims, which decision brought about the Sherley amendment of August 23, 1912, prohibiting the making of false or fraudulent statements on labels and packages regarding the curative or therapeutic effect of the article being sold or any of its ingredients. The *Johnson* case did however establish the doctrine, currently recognized, that manufacturers and vendors of preparations are not criminally liable for the praises of others, even though mistaken, where such commendation was not exploited by the manufacturers and vendors for their profit.

Even had the forces set in motion by the government agents resulted in creating the impression that Millrue had value in the treatment of disease, the consequence of such action on the part of the government cannot be imputed to the Petitioners, so as to establish intendment on their part that Millrue had therapeutic value.

The exchange of communications between Agents Armstrong and Forbragd and the Petitioners herein, as aforesaid, cannot therefore be regarded as a relevant source for the purpose of determining the conditions and purposes for which Petitioners offered their product.

Nor can the article appearing in the magazine "Herald of Health," be regarded as a relevant source, since

the praises therein were not used in any manner by the Petitioners in the distribution of Millrue.

The Petitioners herein were not aware of the preparation and publication of the magazine article. When they learned of the context of the article after its publication, the Petitioners immediately instructed local counsel to prepare a disclaimer which was mailed to those who inquired about and/or ordered Millrue as a result of the magazine article.

The government was unable to minimize the true meaning of the positive assertion in the disclaimer that "no claim is made that the product cures anything, either by the writer, or the manufacturer." The government did successfully convince the appellate court that the "statement in the disclaimer letter that 'Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom,' within the factual context present here, does not shield defendants from the consequences of their wilful acts." Thus, local counsel, in incorporating the above quoted sentence in the disclaimer, merely expressed a freedom that is enjoyed in this Country, but the appellate court regarded the disclaimer as being "framed with the intention of drawing a cloak of legality around defendants' transactions."

As to the question of entrapment, the Petitioners submit that injustice resulted from the failure of the trial court to rule that entrapment had been established as a matter of law, and that the refusal of the appellate court to consider this question for the first time on appeal leads to a miscarriage of justice. *United States* v. *Sferas*, supra, 210 F.2d 69 (7th Cir. 1954).

The doctrine of entrapment is revealed in the following statement of the Supreme Court of the United States, and is pertinent to the instant cause:

> The defense is available, not in the view that the accused though guilty may go free, but that the Government cannot be permitted to contend he is guilty of a crime where the government official are the instigators of his conduct.

Sorrells v. *United States,* 287 U.S. at 452, and *Sherman* v. *United States,* supra, 356 U.S. 369 (1958).

In the present cause, the acts complained of, which ultimately were the sole basis for the appellate court decision, were the two transactions with Petitioners by Agents Armstrong and Forbragd of the government. Despite gross annual sales of some fifty to sixty thousand dollars of Millrue, the government was obliged to rely on the two transactions, aforesaid, in the prosecution of this case. And, in those two transactions, government officials were themselves the instigators of the conduct of Petitioners.

In all of the thousands of dollars of sales of Millrue to ordinary customers, not challenged by the government, no therapeutic claims for the product were made by the Petitioners, and in these sales, the product so distributed, was a dietary food supplement, properly labeled as such. Thus, Petitioners were neither engaged in criminal activity at the time the government instituted its stratagem, nor were the Petitioners awaiting any propitious opportunity to commit the offense of making therapeutic claims for Millrue, thereby transferring a food product into the category of a drug, and introducing a misbranded drug into interstate commerce.

That Petitioners were not awaiting an opportunity to commit the offense charged, nor were they predisposed to do so, is further evidenced by the efforts of Petitioners to disclaim the commendations appearing in the magazine article. Even in the two transactions complained of by the government, the sale of Millrue in each of these transactions was not consummated until disclaimers had been sent, or made known, to each inquirer, and re-orders submitted on the basis of the disclaimers.

In *Hansford* v. *United States*, 112 U.S. App. D.C. 359, 303 F.2d 219, the statement of Judge Learned Hand in *United States* v. *Sherman*, 200 F.2d 880 (2d Cir. 1952), was quoted as follows:

> In such cases two questions of fact arise: (1) did the agent induce the accused to commit the offence charged in the indictment; (2) if so, was the accused ready and willing without persuasion and was he awaiting any propitious opportunity to commit the offence. On the first question the accused has the burden; on the second the prosecution has it.

It is most significant that in the instant case, Petitioners were committing no federal offense in the sale of Millrue immediately prior to the ruse of the government agents. In fact, the sale of Millrue as a dietary food supplement, complied with all pertinent federal statutes. The offense charged was the alleged sale by Petitioners of Millrue for the treatment of disease. Such a sale on that premise, even if such premise was imputed to Petitioners, was induced by government officials. Unlike the ordinary narcotic cases, where the sale of such product is illegal, the sale of a harmless food supplement, as such, is legal, unless and until the

vendor makes therapeutic claims for the product and that use is not included in the product's labeling. Petitioners made no such claims to the two government officials. Rather, these officials set in motion the claims complained of, induced the Petitioners to sell Millrue under those circumstances, and then charged the commission of an offense.

The very preparation of a disclaimer by the Petitioners, and its circulation as aforesaid, negates the premise that the Petitioners were awaiting a propitious opportunity to sell Millrue as a drug.

Nor while Petitioners might have been ready and willing to sell Millrue to the government agents as a food supplement, Petitioners were clearly induced to commit the offense charged, and the origin of the criminal design in this case was with the government.

CONCLUSION

For the reasons stated, and under the authorities cited, it is submitted that the decision of the United States Court of Appeals for the Seventh Circuit was and is in error, in affirming the judgment entered by the District Court convicting defendants on Counts III and V, of the Indictment, and that this Petition for a Writ of Certiorari to that Court to review its action in so holding, as herein sought, is well founded in fact and in law and should be granted.

Respectfully submitted,

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APPENDIX

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

No. 13752 SEPTEMBER TERM, 1962 SEPTEMBER SESSION, 1962

UNITED STATES OF AMERICA, *Plaintiff-Appellee*,

v.

MILLPAX, INC., A CORPORATION, AND ROY F. PAXTON, AN INDIVIDUAL, *Defendants-Appellants*.

Appeal from the United States District Court, Southern District of Illinois, Southern Division

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January 15, 1963

Before SCHNACKENBERG, KNOCH and SWYGERT, *Circuit Judges*.

SWYGERT, *Circuit Judge*. Defendants, Millpax, Inc., and Roy F. Paxton, were found guilty after trial by jury on three counts of a five-count indictment charging them with the misbranding of a drug known as "Millrue," in that its labeling failed to bear adequate directions for use as required by Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U. S. C. § 352(f)(1), and with causing the introduction or delivery for introduction into interstate commerce of such preparation, so labeled, in violation of Section 301(a) of the Act, 21 U. S. C. § 331(a), which prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded.

Defendant Millpax, Inc., until March 23, 1961, was a corporation organized and existing under the laws of the State of Illinois, with office and principal place of business at Carlock, Illinois. Defendant Roy F. Paxton was secretary-treasurer and principal stockholder of the corporation.

The product in question was packaged in bottles, bearing labels displaying the following printed and graphic matter:

Millrue
Iron Tonic
Hematinic
Stomachic
Contents 8 Fl. Oz.
Manufactured by
Millpax, Inc.
Carlock, Illinois

The errors relied on for reversal arise out of the claimed inadequacy of the evidence to support the verdict, the charge to the jury (which was not objected to), and the failure of the trial court to acquit the defendants on the ground that, as a matter of law, they were entrapped.

On October 7, 1958, the same two defendants were convicted on a plea of guilty for the interstate distribution of "Mill Rue Tonic Hematinic Stomachic" with labeling that falsely represented it to be effective in the treatment of cancer, ulcers, kidney troubles, and bladder troubles. Both defendants in that case paid fines. This Court may properly take judicial notice of the Notice of Judgment reporting the conviction published pursuant to 21 U. S. C. § 375(a). *Colgrove v. United States*, 176 F. 2d 614 (9th Cir. 1949).

On May 2, 1960, Charles Armstrong, a Federal Food and Drug Inspector, wrote defendant Paxton from Memphis, Tennessee, ordering two bottles of Millrue. He enclosed a ten dollar money order. He stated in his letter that he had just been informed that he had cancer, and that he had

read in the "Herald of Health" magazine about "your cancer cure—Millrue." In response to his letter, he received a form letter,[1] prepared and signed by defendants' attorney, directing him to reread the article and to note that no claim is made by the writer or the manufacturer that Millrue cures anything. Concerning the claims made in the magazine article, the form letter to Inspector Armstrong said "Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusions therefrom." It is evident that the form letter was framed with the intention of drawing a cloak of legality around defendants' transactions. While there is a disclaimer in the letter as to any

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[1] The alleged disclaimer letter reads as follows:

"Many thanks for your letter and order and it is regretted that Mr. Paxton cannot write to you personally as the mail has been tremendous and the Company is a small one.

"Your interest in the article referred to is natural, but terming the product a "blood purifier" therein is a misnomer. To "purify" connotes that as to any particular substance it is freed from extraneous matter or from anything that debases, pollutes, or contaminates it. The blood may be variable through bodily functions or malfunctions, and by ingestion, deficiencies when existent may be aided.

"If you will again read the article referred to which was written by Don C. Mottham, you will find that no claim is made that the product cures anything, either by the writer or the manufacturer. Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom.

"If you still desire to order please advise by return mail, otherwise your money will be returned to you, as there is no desire by the manufacturer to sell this product under false pretenses.

"Sincerely,

Millpax, Inc.,

By

Theodore W. Hinds"

claims made directly by defendants, the jury is not required to blind itself to reality and fail to recognize the obvious intent of such a letter to adopt the testimonials made by others. No other purpose could be implied in view of the fact that the order from Armstrong specifically mentioned that he was suffering from cancer and that he wanted the Millrue to forestall his having to submit to surgery. We think it reasonable to recognize the plight of those suffering from cancer, their desperate frame of mind of which "cancer remedy" salesmen are undoubtedly aware and the influence these complementary attitudes have on a transaction such as the one in question. It is obvious that defendants intended to be understood as adopting as their own the magazine testimonials. The statement in the disclaimer letter that "Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom," within the factual context present here, does not shield defendants from the consequences of their wilful acts.

Armstrong, upon receipt of the form letter, wrote another letter requesting the Millrue. In response thereto he received a package in the United States Mails from Millpax, Inc., containing two bottles of Millrue.

Both defendants were charged in Count III with responsibility for this interstate shipment of a misbranded drug.

Defendants contend that the preparation known as Millrue is not a drug, but is a food for special dietary use excepted by the Federal Food, Drug, and Cosmetic Act, as amended, from inclusion in the term "drug." As discussed above, however, the intention of the defendants was to have prospective purchasers regard it as a drug and so use it; hence, their own actions classified Millrue as a drug. Thus, the use of the term "drug" as used in the indictment and during the trial could not have been prejudicial to defendants.

On April 16, 1960, Inspector Gebhart from the St. Louis office of the Food and Drug Administration and Mrs. Rachel Harrington, a clerical employee of that office, visited defendants' place of business at Carlock, Illinois. They posed as a married couple from Memphis, Tennessee, and indicated they came to Carlock to see if defendant Paxton could find out what was wrong with Mrs. Harrington. They did not suggest to Paxton that she was suffering from any specific disease or ailment.

Paxton asked her to sit on a couch. As soon as she was seated, he began examining her left foot. When he examined the third toe, he told Mrs. Harrington that she had gas on the upper colon which is usually where cancer starts. In response to being asked if she had cancer, he stated that she did. Paxton recommended his Millrue tonic for this condition. He recommended also that she follow a diet and he gave her a printed copy of the directions for such diet. He told her that he had never lost a case of cancer or leukemia, and that she would be all right in three months. He also related that he had acquired the formula for Millrue about forty years ago from an Old India doctor who wanted him to marry his daughter. The diet list and the label on the bottle were the only written directions given the agents for use of Millrue. Agent Gebhart and Mrs. Harrington purchased six bottles of Millrue, and departed. Count IV of the indictment charged defendants with having caused to be delivered to Gebhart and Mrs. Harrington for introduction into interstate commerce the misbranded drug.

A showing that drugs were introduced into interstate commerce is sufficient to show that they were, as well, delivered for introduction into interstate commerce. *United States v. Urlikon Products Co.*, 185 F. 2d 3 (7th Cir. 1950).

The government contends that where a misbranded drug is sold and the seller has knowledge that the purchaser intends to transport the drug to another state, this knowl

edge, in and of itself, is sufficient to bring the transaction within the ambit of 21 U. S. C. § 331(a), i.e., that the sale is an introduction or delivery for introduction into interstate commerce of the misbranded drug. It relies for support of this contention on *Drown* v. *United States*, 198 F. 2d 999 (9th Cir. 1952), cert. denied, 344 U. S. 920; and *United States* v. *Sanders*, 196 F. 2d 895 (10th Cir. 1952). For our purposes we need not decide if these cases support the broad interpretation given to 21 U. S. C. § 331(a) by the government.

While it is true that defendant Paxton not only sold the misbranded product to the government agents and did so intending that it would be taken by them to Tennessee, this intention was and could only have been formulated as a result of a representation made by the government agents which the evidence shows had no basis in reality. If we are to assume that the seller participates in some degree in the intent of the buyer so as to make the buyer's intent his intent, then we must also assume that, where a material misrepresentation by the buyer is made that the transaction is of an interstate character, a federal crime based on interstate commerce cannot exist. If this were not so, government agents would be able to turn a purely "over the counter" sale of a misbranded product into a federal crime merely by an off-hand statement, completely untrue, that they intended to transport the goods across a state line. Here there was no evidence that Gebhart or Harrington came from Tennessee, intended to return to Tennessee, or had ever been in Tennessee. In fact, the evidence is conclusive that St. Louis, Missouri was their point of origin and also their destination when they left Carlock after making the purchase.

The fact that they did cross a state line is immaterial in a situation where the crime is made federal only by virtue of the wrongdoers' participation in their expressed intent. The only intent ever expressed was totally false and we

decline to extend defendants' knowledge of the agents' intent to that deliberately concealed so as to make them aware of the interstate nature of the sale. If this seems a formalism, it is a formalism required under our federal system—particularly where the statute specifically calls for an introduction or delivery for introduction into interstate commerce as a requirement and essential element of the corpus delicti. Situations not involving interstate commerce are not before us and we specifically decline to treat them. *Cf. United Cigar Wholesale Stores Corp.* v. *United States*, 113 F. 2d 340 (9th Cir. 1940); *Sherman* v. *United States*, 10 F. 2d 17 (6th Cir. 1926); *United States* v. *Abda*, 32 F. Supp. 23 (D. C. M. D. Pa. 1940). We are concerned solely with a statute that defines a criminal act under the cognizance of federal authority having as an essential element thereof knowledge of or intent to engage in or affect interstate commerce and actions commensurate with such knowledge or intent.

We think that the interstate element of the crime must rest on something more solid than the pretenses of government agents to satisfy the minimum requirements of basic fair play—that is, due process. Since the interstate element of Count IV was not proved, we hold that the conviction under that count must be vacated.

On May 6, 1960, Jack A Forbragd, an Inspector stationed in San Francisco, addressed a letter to defendant Paxton requesting a bottle of Millrue. The letter stated that he had stomach pains, was constipated, and was sure he had cancer. It further stated that he had read in the "Herald of Health" magazine that Millrue was a cancer cure. He enclosed a money order for $5.20. In response, he received a bottle of Millrue. The labeling contained no reference to cancer, stomach pains or constipation. Defendants, at the trial, attempted to show that a disclaimer letter, worded identically to that sent to Inspector Armstrong, was mailed to Inspector Forbragd. Moreover, Pax-

tor testified that Forbragd in a telephone call from San Francisco acknowledged receipt of the form letter and nonetheless ordered the drug. Forbragd denied receipt of any such letter or that he had made the telephone call. On cross-examination of defendants' witnesses, it was brought out that no attempt had been made to find a record of the telephone call; that the person who allegedly mailed the letter didn't remember mailing it; and that the carbon introduced and claimed to be a copy of the form mailed to Forbagd may have been prepared solely for the purposes of trial. The Forbragd sale was the basis for Count V of the indictment charging defendants with having caused to be introduced and delivered for introduction into interstate commerce a drug misbranded in that its labeling failed to bear adequate directions for use for the purposes and conditions for which the drug was intended, namely, the treatment of stomach pains, constipation, and cancer.

It is elementary that where the ground for reversal is insufficiency of the evidence to support the verdict, the evidence must be construed in the light most favorable to the government and in the light of all reasonable inferences which the jury may draw therefrom. *Glasser* v. *United States*, 315 U. S. 60 (1942). Although defendants introduced versions of the transactions in question different from those of the government, we are convinced that the jury was justified in accepting the government's proof. There is substantial evidence to support the verdict as to Counts III and V

Defendants, on appeal, raise for the first time the defense of entrapment as a matter of law. It is uniform practice for appellate courts to refuse to consider alleged errors not raised in the trial court unless the result would lead to a miscarriage of justice. *Ramirez* v. *United States*, 294 F. 2d 277 (9th Cir. 1961); *United States* v. *Sferas*, 210 F. 2d 69 (7th Cir. 1954), cert. denied, 347 U. S. 935. We are convinced that no injustice resulted from the failure of the

trial court to rule that entrapment had been established as a matter of law. Entrapment as a matter of law is established only where undisputed testimony makes it patently clear that an otherwise innocent person was induced to commit the act complained of by the trickery, persuasion, or fraud of a government agent. *Sorrells* v. *United States*, 287 U. S. 435 (1932). We believe the previous conviction and the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that government agents used a ruse to conceal their identity does not require a different conclusion. The issue of entrapment was properly left to the jury.

We have examined the instructions given by the trial judge and find them to have correctly stated the issues and the law governing the case. The instructions were not objected to at the trial and in the absence of substantial error capable of resulting in a miscarriage of justice we decline to consider the assignments of error now raised for the first time on appeal. *United States* v. *Vason*, 222 F. 2d 3 (7th Cir. 1955).

The judgment entered by the District Court convicting defendants on Count IV is reversed. The judgment convicting defendants on Counts III and V is AFFIRMED.

A true Copy:

Teste:

.....

Clerk of the United States Court of Appeals for the Seventh Circuit.

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
Chicago 10, Illinois

Thursday, February 21, 1963

Before HON. ELMER J. SCHNACKENBERG, *Circuit Judge*,
HON. WIN G. KNOCH, *Circuit Judge*, HON. LUTHER M.
SWYGERT, *Circuit Judge*.

No. 13752

UNITED STATES OF AMERICA, *Plaintiff-Appellee*,

vs.

MILLPAX, INC., ET AL., *Defendants-Appellants*.

Appeal from the United States District Court for the
Southern District of Illinois, Southern Division.

On consideration of the petition for rehearing filed herein by counsel for defendants-appellants,

IT IS HEREBY ORDERED that the opinion of this Court dated January 15, 1963, in the above entitled cause be changed as follows:

Page 2—Delete the third full paragraph reading:

> "On October 7, 1958, the same two defendants were convicted on a plea of guilty for the interstate distribution of 'Mil Rue Tonic Hematinic Stomachic' with labeling that falsely represented it to be effective in the treatment of cancer, ulcers, kidney troubles, and bladder troubles. Both defendants in that case paid fines. This Court may properly take judicial notice of the Notice of Judgment reporting the conviction published pursuant to 21 U.S.C. § 375(a). Colgrove v. United States, 176 F.2d 614 (9th Cir. 1949)."

Page 7—Delete the words reading, "the previous conviction and," appearing in the fifth sentence in the second full paragraph. The sentence will then read:

> "We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that the government agents used a ruse to conceal their identity does not require a different conclusion."

It Is Further Ordered that the petition for rehearing of this cause be, and the same is hereby, Denied.

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APR 8 1968

No. 911

In the Supreme Court of the United States

OCTOBER TERM, 1967

[redacted], and Ray V. Parris,
Petitioners,

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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In the Supreme Court of the United States

OCTOBER TERM, 1962

No. 911

MILLPAX, INC., A CORPORATION, AND ROY F. PAXTON, AN INDIVIDUAL, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. 1a–11a) is not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on January 15, 1963, and a petition for rehearing was denied on February 21, 1963. The petition for a writ of certiorari was filed on March 8, 1963. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the evidence is sufficient to sustain the determination of the jury that petitioners' product "Millrue" was misbranded because its labeling failed to bear adequate directions for its use.

2. Whether the defense of entrapment, which was rejected by the jury, was established as a matter of law by evidence that Food and Drug Administration agents ordered the product without identifying themselves as government agents.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. 301, *et seq.*, provides in pertinent part:

> Section 301 [21 U.S.C. 331]. The following acts and the causing thereof are prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.
>
> * * * * *
>
> Section 502 [21 U.S.C. 352]. A drug or device shall be deemed to be misbranded—
>
> * * * * *
>
> (f) Unless its labeling bears (1) adequate directions for use * * *.
>
> * * * * *

21 CFR 1.106(a) provides in pertinent part:

> (a) *Adequate directions for use.*
>
> "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inade-

quate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising * * *.

* * * * *

STATEMENT

Petitioners, Millpax, Inc., a corporation, and Roy F. Paxton, secretary-treasurer of the corporation, were convicted, after trial by jury, on counts 3, 4, and 5, respectively, of a five-count indictment charging introduction of misbranded drugs into interstate commerce. The misbranding alleged was that the labeling failed to bear adequate directions for use, since it failed to state the purposes, conditions, and diseases for which the drug was intended to be used. The judgment on count 4 was reversed on appeal. On the other two counts, Paxton was sentenced to imprisonment for three years on one, and to three years' probation and $2,500 on the other. Millpax was fined $500 on each count (D.A. 136–138).[1]

The drug involved in each count was called "Millrue." Petitioner Millpax labeled it simply as a dietary food supplement, effective in aiding deficiencies in iron, vitamins B1 and B2, and niacin (Gov. Exs. 4, 9, 10, 11–16; G.A. 17). Petitioner Paxton stated that

[1] "G.A." and "D.A." refer, respectively, to the government's and petitioners' appendices in the court of appeals.

Millrue was useful for the treatment of cancer and its symptoms during interviews with prospective purchasers at the offices of Millpax in Carlock, Illinois (D.A. 28–34, 47–50) and similar claims were made in a magazine article in the March 1960 issue of "Herald of Health" (D.A. 5).

1. The facts with respect to the particular two interstate shipments here involved are as follows:

a. On May 2, 1960, Charles Armstrong, a Federal Food and Drug Inspector, wrote Paxton from Memphis, Tennessee, ordering two bottles of Millrue and enclosing a ten-dollar money order. He said in his letter that he had just been informed that he had cancer, and that he had read in the "Herald of Health" magazine about "your cancer cure—Millrue" (D.A. 23, 121). In response, he received a form letter prepared in March 1960 by petitioners' attorney, Hinds, in anticipation of inquiries resulting from the magazine article (D.A. 71, 82). All mail mentioning any diseases or the "Herald of Health" was forwarded to attorney Hinds (D.A. 86).

The form letter directed Armstrong to reread the article and to note that no claim is made by the writer or the manufacturer that Millrue cures anything (Gov. Ex. 7; D.A. 26). Concerning the claims made in the magazine article, the form letter said: "Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom" (Gov. Ex. 7; D.A. 26). On May 10, 1960, Armstrong wrote the corporation in Illinois to send the drug (D.A. 24, 122), and he re-

ceived, in Tennessee, two bottles of Millrue from the defendants on May 20, 1960 (D.A. 24, 25). This shipment constituted the basis for count 3.

b. On May 6, 1960, Jack A. Forbragd, an Inspector stationed in San Francisco, addressed a letter to petitioner Paxton requesting a bottle of Millrue and enclosing a money order for $5.20 (D.A. 5–6). In his letter, he stated that he had stomach pains, was constipated, and was sure he had cancer. He also stated that he had read in the "Herald of Health" magazine that Millrue was a cancer cure (D.A. 5–6). In response to this letter, he received a bottle of Millrue (D.A. 6). The labeling of the drug contained no reference to cancer, stomach pains, or constipation (Gov. Ex. 4; G.A. 17).

Petitioners attempted to show that a disclaimer letter, worded identically to that sent to Inspector Armstrong, was mailed to Inspector Forbragd (D.A. 75). Paxton testified that Forbragd in a telephone call from San Francisco acknowledged receipt of the form letter and nonetheless ordered the drug (D.A. 89). Forbragd denied receipt of any such letter (D.A. 7, 9, 11, 12), and stated that he had never telephoned petitioners or their agents (D.A. 7, 9). On cross-examination of petitioners' witnesses, it was brought out that no attempt had been made to find a record of the alleged telephone call (D.A. 103); that the person who allegedly mailed the letter did not remember mailing it (D.A. 79); and that the carbon introduced and claimed to be a copy of the form mailed to Forbragd may have been typed solely for the purposes of trial

(D.A. 79). This transaction was the basis for count 5.

2. The case was submitted to the jury on a lengthy charge which had been approved by counsel for both parties (D.A. 107–118; G.A. 8). The judge instructed the jury that it would have to consider all the facts to determine whether Millrue was a drug intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (D.A. 108–109) and whether, if a drug, it was misbranded for failure to bear adequate directions for use (D.A. 109). He told the jury to consider not whether the buyers intended the drug for cancer, stomach pains, and constipation, but whether petitioners intended it to be so used (D.A. 116, 117–118). On the issue of entrapment, the jury was told that the issue was whether petitioners were ready and willing to commit the crime and the government agents merely afforded them the opportunity or whether petitioners had no previous intent or willingness to commit the crime and did so only because of the inducement of the government agents (D.A. 113).

ARGUMENT

1. Section 502 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352, *supra*, p. 2, provides that a drug "shall be deemed to be misbranded * * * [u]nless its labeling bears * * * adequate directions for use * * *." The regulations promulgated under this section, 21 CFR 1.106(a), *supra*, pp. 2–3, state that "adequate directions for use" requires a statement "of all conditions, purposes, or uses for which such drug * * * is intended * * *." The evidence is

plain and undisputed that the substance involved in this case, Millrue, did not carry labeling stating that it was intended for use in the treatment of cancer or any other disease. Petitioners' contention is that Millrue was a food product, not a drug for the treatment of diseases. This factual issue, however, as to whether petitioners intended that Millrue be used as a drug, was submitted to the jury under instructions which are not questioned. The resolution of that issue by the jury presents no question warranting review by this Court.

Moreover, the evidence clearly supports the jury's determination. Petitioner Paxton, the secretary-treasurer of petitioner Millpax, described Millrue to prospective purchasers as useful in the treatment of cancer. This evidence is alone sufficient to show that petitioners were selling Millrue as a drug. In addition, an article appeared in "Herald of Health" making the same claim. While there is no evidence in the record that petitioners were themselves responsible for this article, it was clearly related to their merchandising. Petitioners, in anticipation of public interest in "Millrue" following national publicity for the product, devised a form letter to be used whenever the magazine article or illnesses were mentioned in the incoming mail. Thus, petitioners were aware that Millrue was widely understood to be a drug for the treatment of cancer. While petitioners' form letter did not claim that the article was correct, it did not disassociate petitioners from it. Thus, the jury could reasonably conclude that petitioners' form letter intended to exploit for Millrue the article's claims

although endeavoring to draw, as the court of appeals stated (Pet. App. 3a), a "cloak of legality" around the transactions by refusing to make any explicit claims of its own. In short, the letter of disclaimer, however artful, could reasonably be deemed to create the impression that representations for Millrue made in the magazine article were not repudiated, but could be relied on by the purchaser.

Petitioners are not being punished for representations by others; they are being punished for their own acts in selling a substance with the knowledge and intent that it be used as a drug without adequate directions for use. There was ample evidence, on which the jury could rely, that petitioners had such intent.[2]

2. The trial court gave the jury complete instructions on the issue of entrapment (D.A. 112–114), to which petitioners did not object. The jury rejected petitioners' factual contentions in finding them guilty. Thus, petitioners' argument here must be that entrapment was established as a matter of law.

We submit that the jury reasonably found on this record that petitioners were not entrapped. This Court has held that entrapment is shown "when the criminal design originates with the officials of the Government, and they implant in the mind of an inno-

[2] This Court's decision in *United States* v. *Johnson*, 221 U.S. 488, is not apposite. There, this Court held that false therapeutic claims were not misbranding under the Food and Drug Act because the Act related only to false statements concerning the identity of the drug. Since that decision, Congress has amended the Act to require in Section 502 that the label include "adequate directions for use * * *."

cent person the disposition to commit the alleged offense and induce its commission in order that they may prosecute." On the other hand, the fact that government agents "merely afford opportunities * * * for the commission of the offense" is not entrapment. *Sorrells* v. *United States*, 287 U.S. 435, 442, 441. See also *Sherman* v. *United States*, 356 U.S. 369, 372–373. Here, the record is devoid of any testimony that petitioners were in any way swayed by entreaties by the government agents in filling their requests. The transactions with inspectors Armstrong and Forbragd were impersonally conducted through the mails. The fact that petitioners had ready a prepared letter shows that they were ready and willing to engage in a mail-order business based on the magazine article. Furthermore, the evidence shows that, in over-the-counter sales to customers from out-of-state, Paxton refused to initial sales receipts for the reason that there was "a Federal agent out snoo[p]ing around" (D.A. 96). Petitioners were clearly not innocents induced to commit crime, but were ready and willing to make sales to whomever desired to buy.[3]

[3] The decision of the Court of Appeals for the District of Columbia in *Johnson* v. *United States* (No. 16890, February 14, 1963) held only that where government funds were used to make a purchase there was enough of a question of entrapment to warrant submission of the issue to the jury.

CONCLUSION

For the foregoing reasons, we respectfully submit that the petition for a writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1962

No. 911

MILLPAX, a Corporation, and
ROY F. PAXTON, an Individual, *Petitioners*,

v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR REHEARING OF ORDER DENYING PETITION FOR WRIT OF CERTIORARI

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IN THE

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OCTOBER TERM, 1962

No. 911

MILLPAX, a Corporation, and
ROY F. PAXTON, an Individual, *Petitioners,*

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UNITED STATES OF AMERICA, *Respondent*

PETITION FOR REHEARING OF ORDER DENYING PETITION FOR WRIT OF CERTIORARI

Petitioners, Millpax, Inc., a Corporation, and Roy F. Paxton, an Individual, pray that this Court grant rehearing of its order of April 29, 1963, denying the petition for writ of certiorari, and that a writ of certiorari issue to review the judgment of the Court of Appeals for the Seventh Circuit in the above-entitled case as prayed for in the petition filed March 8, 1963.

REASONS FOR GRANTING REHEARING AND ISSUING THE WRIT

1. Petitioners submit that the action of this Court of April 29, 1963, could only have resulted from a lack of clarity with respect to the arguments advanced by Petitioners in the original petition for certiorari, and for the first primary reason, petition for rehearing should be granted. *Hickman* v. *Taylor*, 327 U.S. 808, 328 U.S. 876, 329 U.S. 495; *Brinkerhoff-Faris Trust Co.* v. *Hill*, 280 U.S. 604, 281 U.S. 673.

The simple facts are, that Petitioner, Roy F. Paxton, is facing six years of imprisonment because users of his product, "Millrue", *a dietary food supplement*, so registered in the U. S. Patent Office, and labeled as such in conformity with the requirements of the Federal Food, Drug, and Cosmetic Act, sang its praises.

Such commendation captured the imagination of the Editor of the magazine "Herald of Health", the context of which was not allowed in evidence by the trial court herein, who wrote and caused to be published in that periodical, without the knowledge, sanction, exploitation or approval of the Petitioners, a feature story of these praises.

Admittedly this story did stimulate inquiries concerning the product, but Petitioners answered in each instance with a reply denying that "Millrue" could cure anything.

Try as it might, the government failed to produce a single witness to testify that "Millrue" had been held forth as having therapeutic value in the treatment of any human ailment.

Resort was finally had to the use of government agents, in two transactions, posing as ordinary mail

order customers (Counts III and V of the Indictment), who cited the magazine story and ordered "Millrue" for faked ailments despite the denial in each transaction by the Petitioners that the product had any curative properties.

In the third transaction (Count IV of the Indictment), co-agents of the government, posing as ordinary "over-the-counter" customers, employed every stratagem in their efforts to prevail on Petitioner, Roy F. Paxton, to sell them "Millrue" for human ailments.

The government, in its Brief in Opposition of petition for certiorari (p. 4) argued that these transactions constituted claims on the part of Petitioners that "Millrue" was useful for the treatment of certain ailments.

The "over-the-counter" (Count IV of the Indictment), *was vacated* by the appellate court herein, Petitioners' conviction on this Count being reversed, yet the government in its Brief in Opposition, *supra* (p. 4), submitted to this Court the premise that the evidence adduced in connection with Count IV, supported its claim that "Millrue" was held forth as useful for the treatment of cancer, despite the testimony of Mrs. Rachel A. Harrington, one of the co-agents of the government in this transaction that she did not recall that Petitioner, Roy F. Paxton, had told her or the accompanying government agent that "Millrue" could cure cancer.

2. Petitioners also urge, as a second primary reason for granting rehearing, a substantial ground available to them, although not previously presented. *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 50. This ground concerns the question as to whether in fact

"Millrue" was misbranded under Section 502 of the Federal Food, Drug, and Cosmetic Act, because of its failure to bear adequate directions for use. This is a requirement under the Act only if the product concerned is a drug in fact or in fiction.

The product was transferred from the category of a special dietary food supplement to that of a drug, only on the argument of the government that, by virtue of the three transactions referred to herein, Petitioners intended their product for use in the treatment of human ailments; and that therefore, "Millrue" was misbranded according to such argument, by reason of failure to bear adequate directions for such use.

The government did not, and could not, contend that "Millrue" was adulterated, dangerous, deleterious or harmful in any respect, nor that the product was worthless, even for the treatment of disease. Indeed, had the product's label included adequate directions for use in the treatment of those ailments faked by the government agents, the charge of misbranding because of that fact would have been wholly unfounded. Therefore, the stratagem of the government was the act that brought about the so-called inadequacy of the label.

Such an interpretation of the drug provisions of the Federal Food, Drug, and Cosmetic Act, is beyond the imagination of man, and the intent of the Congress when the Act was enacted.

If this Court denies certiorari herein, the food, drug, and cosmetic industries will be at the mercy of the government if their products are innocently praised by the consuming public, in the event the government considers such praise as not being well-founded,

regardless of the fact that the manufacturers do not exploit these commendations to their financial gain, as was the case with the producers of "Milltrue".

3. The fines and punishments imposed on the Petitioners herein are inded excessive, cruel and unjust, and clearly violate the 8th Amendment to the United States Constitution.

No good can come from a denial of a rehearing and the issuing of the writ in this cause.

Faith in government at this point, faith in the veracity, the objectiveness, the accuracy of government agents at this level, in affairs such as these, are the priceless, irreplaceable ingredients of democratic government. We should brook no loose handling in these mundane but delicate matters. If executive officials fail here, or grow autocratic, the judicial branch of government must bring them within the confines of their duty. *C. Broughan* v. *Blanton Mfg. Co.*, 249 U.S. 495, 500; *Houston* v. *St. Louis Packing Co.*, 249 U.S. 479, 483-484. *Armour & Co. (Appellant)* v. *Orville L. Freeman, Secretary of Agriculture, et al.*, No. 16,723, United States Court of Appeals for the District of Columbia Circuit.

CONCLUSION

For the reasons set forth above and in the petition for writ of certiorari, it is respectfully urged that rehearing be granted and that, upon such rehearing, a writ of certiorari issue to the Court of Appeals for the Seventh Circ[illegible].

Respectfully submitted,

CHARLES ORLANDO PRATT,
Counsel for Petitioners.

CERTIFICATE OF COUNSEL

I hereby certify that the foregoing petition for rehearing is presented in good faith and not for delay and is restricted to grounds specified in Rule 58 of the rules of this Court.

CHARLES ORLANDO PRATT,
Counsel for Petitioners.